REMARKS/ARGUMENTS

Initially, the Applicants respectfully petition for reconsideration and withdrawal of the Examiner's Office Action as final inasmuch as the Examiner has rejected all of the pending claims in the present patent application over various new prior art references not previously cited or known to the Applicants, and have not given the Applicants a chance to address this prior art. In other words, the Examiner as set forth a plurality of new grounds of rejection to which Applicants have not had an opportunity to respond. More importantly, the new grounds of rejection were clearly not necessitated by Applicants' prior amendment of the claims, inasmuch as the cited prior art could have been cited earlier by the Examiner if she had known about the art herself since the amendments simply used language from various dependent claims and placed the language into the independent claims. That is, the amendments previously presented were already set forth in the claims of the present application. Accordingly, Applicants believe the finality of the Office Action is premature.

Essentially, the Examiner is limiting Applicants ability to make amendments and arguments that would place the application in better condition for allowance by requiring an After Final response rather than allowing Applicants the opportunity to set forth their position on the prior art. To the extent that any amendments and arguments presented herein raise new issues, such new issues are believed to be the direct result of the Examiner's additional searching for art not previously known to her or the Applicants. While the Applicants understand that applicants who dally in the prosecution of the application in order to keep the application pending before the Examiner should not be able to ward off a final rejection, that is not the case in this instance. In fact, it is to the benefit of the Office and the Applicant to have a compact prosecution where all issues are addressed prior to making Office Actions final. Requiring the Applicants to respond to prior art references discovered and cited by the Examiner for the first time in a final Office Action, defeats the Office's policy of providing for compact prosecution of the application, clearly lengthening the prosecution process and contributing to an inefficient and more costly

patent prosecution. For these reasons, Applicants respectfully petition the Examiner to reconsider and withdraw the finality of this Office Action.

Turning to the rejections set forth in the Office Action, the Examiner first has rejected claims 1 and 6 under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the claims contain subject matter, namely the phrase "as of February 5, 2002", which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, has possession of the claimed invention.

The Applicants respectfully traverse this rejection. The present patent application was filed on February 5, 2002. Thus, common sense dictates that a disclosure that conveys "a neutralizer designated by the FDA as a direct food substance that is Generally Recognized As Safe" also implicitly, if not inherently, conveys that the neutralizer was designated by the FDA as of February 5, 2002 when the application was filed on that date. To assert otherwise, ignores the intent, the objective, and the basic premise of the application. Clearly, one skilled in the art would implicitly, if not inherently, understand from reading the application that Applicants had possession of that subject matter, namely the date of the filing of their application, at the time the application was filed. If it is not conventional and reasonably conveyed that the FDA designations were to be construed from the date of filing of the application, *i.e.*, as of February 5, 2002, then the Examiner is asserting that one cannot reasonably convey possession of something at the time of filing of the application. This would mean that nothing could ever be reasonably conveyed to one skilled in the relevant art. As there is no prohibition against amending claims to include subject matter that is implicit or inherent from a fair and reasonable reading of the specification, it is believed that this previous amendment complies with the written description requirement of the U.S. patent laws. Each claim limitation is expressly, implicitly, if not inherently, supported in the originally filed application. MPEP 2163.05.

Next, the Examiner rejects the same claims under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner asserts that the FDA guideline is not permanent, and therefore, the scope of the claim is uncertain. In addition, the Examiner asserts that the Applicants are incorporating essential subject matter into the application by reference.

The Applicants respectfully traverse this rejection. The addition of the date of filing of the application, *i.e.*, February 5, 2002, makes the FDA designations permanent. That is, one of skill in the art would readily understand and know what neutralizers are Generally Recognized As Safe (also referred to hereinafter as "GRAS") by the FDA on the date the application was filed. Those neutralizers will not change and cannot be changed, even if the FDA guideline is eventually changed, since the claims required the use of those ingredients designated as GRAS as of February 4, 2002. Again, it is those neutralizers set forth by the FDA as GRAS as of the filing date of the application. Therefore, the scope of the claims is indeed certain. Moreover, while the FDA designations may be a guideline, and not permanent over a period of years, since laws change, the designation as now set forth in the claims are permanent since a date certain is given, and any person skilled in the art can determine exactly which of these neutralizers were designated by the FDA as GRAS as of that date certain.

Still further, describing the neutralizers with reference to the FDA designation as GRAS neutralizers does not incorporate them by reference. The description of the neutralizers using the GRAS designation is nothing more than the Applicants attempt to set forth a clear, concise, and definite designation already accepted by the one department of the United States government (i.e., the FDA), in a manner which would not require the listing of more than 800 different chemicals in order to adequately convey those ingredients which are considered to be a part of the group of neutralizers claimed. Such a designation is acceptable practice for differentiating this group of neutralizers from another group. In fact, the Applicants of the present application refer to these neutralizers as GRAS neutralizers all the time to differentiate these FDA-acceptable neutralizers from other non-GRAS neutralizers. To

the extent that the Examiner asserts that the subject matter is essential, the Applicants agree, but only to the extent that the essence of the invention requires a differentiation between GRAS neutralizers and non-GRAS neutralizers. They are not attempting to incorporate anything by reference. Should the Examiner believe it is necessary, the Applicants can recite all approximately 800 chemicals designated as Generally Recognized As Safe by the FDA as of February 5, 2002, but that would make the claims much more complicated and, in Applicants' opinion, less clear, and no more definite than it already is. As the Examiner will appreciate, the FDA and the patent application both refer to "Generally Recognized As Safe" as a designation, not a list to be incorporated by reference. Accordingly, the Applicant respectfully requests the Examiner to reconsider and withdraw her rejection of claims 1 and 6 on this basis.

With respect to the prior art rejections, the Examiner has rejected claims 1-7, 9-10, 12 and 25 as being anticipated by Samour et al. U.S. Patent No. 5,976,566; claims 1-2, 4-7, 9, 12 and 25 as being anticipated by McKenzie et al. U.S. Patent No. 5,747,021; and claims 1, 4-7, 9 and 25 as being anticipated by Sequerira et al. U.S. Patent No. 4,775,529. Claim 8 has been rejected over Samour et al. in view of the BF Goodrich technical disclosure.

The Applicants respectfully traverse each of these rejections as well. First, the Examiner asserts that Samour et al. teach a topical alcoholic gel containing 55-70% ethanol, isopropanol or mixture thereof; 0-2% cellulosic thickener, and a base to adjust the pH of the formulation. Sodium hydroxide is noted to neutralize the formulation disclosed therein. Moreover, a Carbopol® carbomer is listed as a possible thickener. Accordingly, the Examiner asserts that all of the elements of the present invention are taught by the reference and that the claimed subject matter is not considered to be patentably distinct over Samour et al.

The Applicants respectfully disagree. Besides the fact that Samour et al. is directed toward formulations suitable for drug delivery through the skin using a penetration enhancer, the patent does not use the recited ethanol, a carbomer polymer, and sodium hydroxide ingredients together in amounts and in a manner which would provide for an alcoholic gel composition like that of the present invention. While the

ingredients are all recited somewhere in the patent, they are not used in a manner to suggest a sanitizing composition that is suitable under the parameters and limitations now set forth in the subject claims. For example, as shown in the Declaration of Dr. Mojgan Cline, sample compositions prepared according to the Samour et al. reference did not produce a viscous gel. Instead, as previously noted, the sodium hydroxide did not succeed in getting the thickener, namely a carbomer polymer, to gel to the desired viscosity where larger amounts (*i.e.*, greater than 60%) of alcohol are also used.

Since it has now been shown that a product manufactured in accordance with Samour et al. would not produce the sanitizing composition of the present invention (see Paragraphs 7-12 of the accompanying Declaration of Dr. Mojgan Cline), it is believed that the claims as presently set forth are patentable over this art.

Next, the Examiner asserts that McKenzie et al. teach a transparent topical composition comprising isopropyl alcohol (30-70%), carbomer (0.25-1.75%), and sodium hydroxide (0.1%) that is available, according to the Examiner, as a gel, lotion, solution, cream, ointment, and so on. Accordingly, the Examiner asserts that all of the elements required by the claims of the present invention are taught by the reference and that the claimed subject matter is not considered to be patentably distinct over McKenzie et al.

Again, the Applicants respectfully disagree for essentially the same reasons as set forth above for Samour et al. First, McKenzie et al. teach an after shave composition comprising water, glycerin, propylene glycol, carbomer, alcohol of various types, acetylsalicylic acid and Peg-8. While the ingredients and, in this case, the order of addition of ingredients are similar to the present invention, there are not identical. Moreover, as now amended, the claims of the present invention are limited to particular aliphatic C1-C4 alcohols, a carbomer thickening agent, and an effective amount of a neutralizer that has been designated by the FDA as of February 5, 2002, as Generally Recognized As Safe or is an amino acid. As shown in the Declaration of Dr. Cline (see Paragraphs 13-18), the sample composition prepared according to the McKenzie et al. reference did not produce a viscous gel. Instead, as previously noted, the sodium hydroxide did not succeed in getting the thickener, namely a carbomer polymer, to gel

to the desired viscosity where larger amounts (*i.e.*, greater than 60%) of alcohol are also used. Thus, the claims of the present invention are believed to be patentable over this cited art.

Next, turning to Sequeira et al., the Examiner asserts that Sequeira et al. teach a topical composition comprising 20-50% propylene glycol, 20-40% isopropyl alcohol, 0.1-3% by weight of a thickener and sodium hydroxide to neutralize the carbomer thickner.

However, Sequeira et al. necessarily uses two types of alcohol (i.e., propylene glycol and isopropyl alcohol), while the present invention has now been limited to at least 60 weight percent of just those aliphatic alcohols have 1 to 4 carbon atoms as now set forth in the claims. Since Sequeira et al. teach only 20-40% isopropyl alcohol, it does not meet the claims of the present invention. Moreover, to the extent the Examiner may attempt to assert that the addition of a greater amount of isopropyl alcohol was be obvious to one of skill in the art, the Applicants point out that, heretofore, it was believed in the art that higher amounts of alcohol could not be used with carbomer thickeners and such GRAS neutralizers. This has repeatedly been shown in the Declaration of Dr. Cline.

Finally, with respect to the Examiner's rejection of claim 8, Applicants do not agree with the Examiner's obviousness assertion and reserve the right to reply to this rejection if needed. However, at the present time, it is believed that the claim from which claim 8 depends, namely claim 1, is patentable over all of the cited art and, therefore, so is claim 8.

In light of the foregoing, applicants respectfully request the Examiner to reconsider the application and withdraw her rejection of the claims. A Notice of Allowance of Claims 1, 3, 5-9, 12 and 25 is earnestly solicited. Should the Examiner care to discuss any of the foregoing in greater detail, the undersigned attorney would welcome a telephone call. A one-month extension request and requisite fee accompanies this response.

Respectfully submitted,

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